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No. 00-19

IN THE

Supreme Court of the United States

SMITHKLINE BEECHAM CONSUMER HEALTHCARE, L.P.,

Petitioner,

v.

WATSON PHARMACEUTICALS, INC.,
WATSON LABORATORIES, INC. and
CIRCA PHARMACEUTICALS, INC.,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

REPLY BRIEF

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I

Petitioner SmithKline Consumer Healthcare, L.P. ("SmithKline") submits this reply brief in response to the brief filed by Respondents Watson Pharmaceuticals, Inc., Watson Laboratories, Inc., and Circa Pharmaceuticals, Inc. (collectively, "Watson)[1] in opposition to SmithKline's petition for a writ of certiorari.

THE COURT OF APPEALS' FAILURE TO HARMONIZE THE GENERIC DRUG LABELING PROVISIONS OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT AND THE COPYRIGHT ACT PRESENTS AN IMPORTANT ISSUE THAT IS LIKELY TO ARISE IN THE FUTURE

In its opposition brief, Watson asserts that this is "a one-of-a-kind case" (Resp. Opp. at 1), one that has "never arisen before" (*id.* at 11), and one that "will not arise in most cases involving the approval of generic drugs" (*id.* at 12) because most generic drug labeling contains largely factual information, not copyrightable creative expression as is contained in the Nicorette® behavioral support materials at issue in this case.

This attempt to minimize the significance of this case is misleading.[2] Although the specific issue presented here — whether section 505(j)(2)(A)(v) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. § 355(j)(2)(A)(v)(1999), which requires the labeling of a generic drug to be "the same

1. Watson's opposition brief is referred to herein as "Resp. Opp."

2. Also misleading, as well as unfair, is Watson's repeated characterization of SmithKline as a monopolist whose purpose in commencing this action was to stifle generic competition. *See* Resp. Opp. at 2, 12, 16. This case is about protecting intellectual property; it is not about monopolization or stifling generic competition. As the record below shows, SmithKline repeatedly urged FDA to allow Watson to make necessary changes in its materials that would allow Watson to reach the market while at the same time preserving SmithKline's copyright rights.

as" that of the pioneer drug, mandates infringement of the copyrightable aspects of pioneer drug labeling — has never before been ruled upon, that fact has no bearing on whether the issue is sufficiently important to warrant review by this Court. Notwithstanding the unusual creativity of the Nicorette® behavioral support materials, and the novelty of SmithKline's legal strategy, the Court of Appeals' decision merits review both because the issue decided is likely to recur with respect to other drugs and because the decision misapplies fundamental principles of statutory construction in holding that one federal body of law (the FFDCA) overrides another (the Copyright Act) without any indication that Congress intended such a result.

1. Although Watson is correct in asserting that the conflict between the FFDCA and the Copyright Act presented in this case has not been ruled upon by a court before and will not arise with respect to purely factual drug labeling, which is devoid of copyrightable expression, it *is*, for example, likely to arise with respect to other over-the-counter (OTC) "lifestyle" drugs that are sold with creative written, audio, or audiovisual materials intended to guide the consumer through a behavioral modification program.

Under the Court of Appeals' ruling, manufacturers of increasingly popular OTC products such as weight loss and hair loss drugs will be deterred from investing significant resources in developing creative behavioral support materials that convey a desired brand image, based on the knowledge that generic competitors will be required to copy that labeling word-for-word.[3] This diminished incentive for drug manufacturers to invest in behavioral support materials is the foreseeable practical consequence of the Court of Appeals' utter disregard for the

3. The fact that this issue will not arise with respect to every generic drug merely underscores fact that accommodating copyright concerns will not impose an undue burden on FDA or undermine the purpose of the expedited generic drug approval process provided for in the Hatch-Waxman Amendments to the FFDCA.

copyright interests implicated by a literal interpretation of the "same as" requirement.

2. Watson mischaracterizes as straightforward and uncontroversial the Court of Appeals' cavalier approach to the reconciliation of conflicting federal statutes. In fact, the court failed to respect the harmonization principle discussed in SmithKline's petition, a failure that bodes ill for copyright protection in other regulatory contexts as well. Specifically, while Watson claims that the Court of Appeals "considered the provisions of the Copyright Act" (Resp. Opp. at 15; *see also id.* at 17) and "appropriate[ly] harmoniz[ed] the two statutes based on the intent of Congress," *id.* at 17, the court did neither. It never looked at the provisions of the Copyright Act. Moreover, while acknowledging that Congress never even considered the statutory conflict presented, the court *assumed* that *had* Congress considered the issue, it *would have* explicitly provided that the Hatch-Waxman Amendments override the Copyright Act. Pet. App. at 17a. Accordingly, rather than harmonizing the statutes as it *purported* to do, the court held that one of them (the Copyright Act) simply does not apply to generic drug labeling.

Thus, in purporting to harmonize the statutes, the Court of Appeals failed even to consider the qualitative distinction between the incentive provided by three-year Hatch-Waxman exclusivity, on the one hand, and the far longer exclusivity provided by the Copyright Act,[4] on the other, in concluding that the incentive to create drug labeling would be unaffected by its ruling.[5] Watson, attempting to justify the Court of Appeals'

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4. Section 303(c) of the Copyright Act, 17 U.S.C. § 302(c) protects works for hire for 75 years from the year of first publication.

5. Watson responds to SmithKline's suggestion that the Court solicit the view of the Copyright Office on the issue presented for review (*see* Pet. at 6 n.1) by claiming that such a request is not necessary because (Cont'd)

faulty harmonization analysis, asserts that copyright protection is unnecessary because the incentive to secure FDA approval "will continue to motivate creative expression in drug labeling" (Resp. Opp. at 14) and because drug manufacturers have a market incentive to make their labeling "attractive, useful, and user-friendly to consumers" (*id.* at 19). This analysis overlooks the fact that the denial of copyright protection eliminates the copyright-based financial incentive to which SmithKline fully expected it would be entitled when it created its materials.

This Court of Appeals' willingness to ride roughshod over the Copyright Act, in the absence of congressional authorization for such an outcome, is of sufficiently serious consequence to warrant review by this Court.

(Cont'd)
the Court of Appeals was "fully apprised of the United States' position as to the copyright issues in the case." Resp. Opp. at 8 n.2. SmithKline respectfully renews its suggestion, on the ground that this case presents a conflict between two bodies of federal law, one of which (the FFDCA) is administered by FDA, an executive branch agency, the other of which (the Copyright Act) is administered by the Copyright Office, a legislative branch agency. FDA, although not a party, was invited by the Court of Appeals to presents its views on this case, but the Copyright Office was not accorded the same opportunity. SmithKline believes it would be appropriate for this Court to do so.

CONCLUSION

For all the reasons set forth above, and in SmithKline's petition for a writ of certiorari, a writ of certiorari should issue to review the judgment of the Court of Appeals for the Second Circuit.

Respectfully submitted,

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